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INSTRUMENTATION AND METHOD FOR PERFORMING IMAGE-GUIDED SPINAL SURGERY USING AN ANTERIOR SURGICAL APPROACH

CROSS REFERENCE TO RELATED APPLICATIONS

The present application is a continuation-in-part of co-pending U.S. Patent Application Serial No. 10/124,291, filed April 17, 2002, the contents of which are hereby incorporated by reference in their entirety.

FIELD OF THE INVENTION

The present invention relates generally to the field of image-guided surgical navigation technology, and more specifically relates to instrumentation and methods for performing image-guided spinal surgery using an anterior surgical approach.

BACKGROUND OF THE INVENTION

Image navigation technology has been developed to indicate and track the relative position of various body parts and surgical instrumentation and implants during medical and surgical procedures. Image navigation systems typically utilize scans obtained either prior to or during a medical or surgical procedure to generate two-dimensional or three-dimensional images of various parts of the body. Such images aid the surgeon in manipulating and guiding surgical instruments, equipment and/or implants during various medical or surgical procedures. Interest in image navigation technology has increased as a result of recent advances in scanning technology, particularly with regard to technological advancements in devices that use computers to generate three-dimensional images, such as computed tomography (CT) or magnetic resonance imaging (MRI).

In the past, use of image navigation technology has been primarily directed to applications involving image guidance systems relating to the cranium. In such applications, the skull provides a convenient reference point for rigid attachment of an image navigation reference device, such as, for example, a surgical navigation reference frame. Recently, image navigation technology has been applied to other areas of the body including the spinal column. Surgical procedures involving the spinal column may be used, for example, to stabilize and/or fuse portions of the spine or to correct various spinal deformities or degenerative conditions. A number of surgical navigation systems have been developed for specific application to surgical procedures involving the spinal column. U.S. Patent No. 6,226,548 to Foley et al. discloses one such system. A similar system is disclosed in U.S. Patent No. 6,236,875 to Bucholz et al.

As illustrated in FIG. 1, surgical procedures involving the spine typically require the formation of a relatively large surgical incision I through the skin S of the patient adjacent the portion of the spinal column to be treated, usually extending along two or more levels of vertebrae V. The size of the surgical incision I must be large enough to accommodate for the manipulation and/or placement of various surgical instruments and implants required for the surgical procedure. Additionally, if image navigation technology is to be used in association with the surgical procedure, the surgical incision I must also accommodate for the mounting of a reference frame or registration device to the spinal column.

As illustrated in FIG. 2, the size of the surgical incision I must be large enough to permit anchoring of an image navigation reference frame or registration device 20 to at least one of the vertebrae V_A. The reference frame 20 is typically anchored to the vertebra V_A via a bone clamp 22 having at least two opposing blades or jaws 24 which include inwardly-facing pointed tips or teeth 26 that provide secure engagement with vertebral bone. The blades 24 are typically clamped about the spinous process 28 of the vertebra V_A to maintain the reference frame 20 in a substantially fixed position relative to the vertebra V_A. The blades 24 are sized to receive the bulb-shaped portion of the spinous process 28 therebetween and the teeth 26 are configured to penetrate into bone tissue for secure fixation thereto. However, if teeth 26 are used to secure the clamp 22 to the vertebra V_A, care must be taken to avoid damage or trauma to the vertebral bone. This is of particular concern when dealing with patient's having soft bone material, such as might be found in older patients or patients afflicted with a bone weakening disease (e.g., osteoporosis). Alternatively, one or more fasteners (not shown) may be used to anchor the reference

frame 20 to the vertebra V_A via insertion into the spinous process 28. However, the use of fasteners to anchor the reference frame 20 to the vertebra V_A requires precise placement to avoid damage to adjacent neural structures, blood vessels and delicate tissue. Moreover, the use of fasteners may result in increased trauma to the vertebra V_A. A fiducial array 30 may also be anchored to the vertebra V_A via the bone clamp 22. The fiducial array 30 provides feedback to the surgical navigation system regarding the precise location of the vertebra V_A by touching a pointed surgical tracker (not shown) against various reference points along the fiducial array 30.

As also illustrated in FIG. 2, mounting of the reference frame 20 directly to the patient's spinal column creates a structural obstruction directly above and around the surgical site that could potentially interfere with or hinder the surgeon during the surgical procedure. Notably, mounting the reference frame 20 to the patient's spinal column must be done in an intra-procedural setting, subsequent to formation of the surgical incision I and commencement of surgery, thereby tending to increase the overall length of the surgical procedure. Moreover, after forming the surgical incision I, the surgeon must stand by and wait while other medical personnel acquire radiographic images of the patient's spinal column. The relatively lengthy wait encountered by the surgeon during this surgical procedure results in inefficient use of the surgeon's time. Additionally, since acquisition of the radiographic images must be done in an intra-operative setting, there is a higher risk of potential infection because the incision must be open for a relatively lengthy period of time.

As discussed above, the use of image navigation systems in surgical procedures involving the spinal column typically requires the formation of a relatively large surgical

incision. Large surgical incisions are highly invasive and can result in increased trauma, blood loss, post-operative pain, and a lengthy recovery period. It would therefore be desirable to provide instrumentation and methods for the mounting of an image navigation reference frame to the patient in a minimally invasive manner to reduce the size of the surgical incision, or by eliminating the surgical incision entirely in applications involving fluoroscopic surgery or percutaneous surgical procedures. It would also be desirable to mount the image navigation reference frame to the patient at a location remote from the surgical site to eliminate structural obstructions above and proximately adjacent the surgical site, thereby providing the surgeon with a relatively unobstructed area to perform the surgical procedure. Moreover, it would be desirable to mount the image navigation reference frame to the patient in a pre-procedural setting at a time prior to formation of the surgical incision and commencement of surgery, thereby reducing the overall length of the surgical procedure and the risks associated therewith. Mounting the reference frame to the patient in a pre-procedural setting would also allow the acquisition of radiographic images without the hindrance of surgical drapes.

Thus, there is a general need to provide improved instrumentation and methods for performing image-guided spinal surgery than is currently available within the industry. The present invention meets this need and provides other benefits and advantages in a novel and unobvious manner.

SUMMARY OF THE INVENTION

The present invention relates generally to instrumentation and methods for performing image-guided spinal surgery using an anterior surgical approach. While the actual nature of the invention covered herein can only be determined with reference to the claims appended hereto, certain forms of the invention that are characteristic of the preferred embodiments disclosed herein are described briefly as follows.

In one form of the present invention, a method is provided for performing image-guided spinal surgery on a patient, comprising providing a surgical navigation reference device, mounting the reference device to bone at a location remote from the patient's spinal column and in a substantially fixed position relative thereto, accessing a portion of the spinal column from an anterior direction, and performing an image-guided surgical procedure on the spinal column using an anterior surgical approach.

In another form of the present invention, a method is provided for performing image-guided spinal surgery on a patient, comprising providing a surgical navigation reference device and a spinal implant, mounting the reference device to bone at a location remote from the patient's spinal column and in a substantially fixed position relative thereto, accessing a portion of the spinal column from an anterior direction, and performing an image-guided surgical procedure on the spinal column using an anterior surgical approach, including removing a portion of a natural intervertebral disc to form an intervertebral opening and inserting the spinal implant into the intervertebral opening.

In another form of the present invention, a method is provided for performing image-guided spinal surgery on a patient, comprising providing a surgical navigation reference device, a bone anchor, and a spinal implant, anchoring the bone anchor to an anterior portion

of the iliac region of the patient's pelvic bone, coupling the reference device to the bone anchor to mount the reference device in a substantially fixed position relative to the spinal column, forming a surgical incision adjacent the lumbar region of the spinal column from an anterior direction, and performing an image-guided surgical procedure on the lumbar region of the spinal column through the surgical incision using an anterior surgical approach, with the image-guided surgical procedure including the removal of a portion of a natural intervertebral disc to form an intervertebral opening and insertion of the spinal implant into the intervertebral opening.

It is one object of the present invention to provide improved instrumentation and methods for performing image-guided spinal surgery than is currently available within the industry.

Further objects, features, advantages, benefits, and aspects of the present invention will become apparent from the drawings and description contained herein.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top view of the back of a patient lying in a prone position, illustrating the formation of a surgical incision above the lumbar region of the spinal column to accommodate a prior art method and apparatus for mounting a surgical navigation reference device to the patient's spinal column.

FIG. 2 is a side view of the spinal column of the patient illustrated in FIG. 1, illustrating the clamping of a surgical navigation reference device to the spinous process of a vertebra.

FIG. 3 is a top view of a cannula according to one embodiment of the present invention for use in association with the mounting of a surgical navigation reference device to a patient.

FIG. 4 is a side view of the cannula illustrated in FIG. 3.

FIG. 5 is a side view of a trocar according to one embodiment of the present invention for use in association with the cannula illustrated in FIG. 3, as used to percutaneously introduce the cannula into the patient.

FIG. 6 is a side view of an insertion instrument according to one embodiment of the present invention, illustrating insertion of the trocar within the cannula.

FIG. 7 is a side view of a bone anchor according to one embodiment of the present invention for use in association with mounting the surgical navigation reference device to the patient.

FIG. 8 is a side view of a mounting instrument according to one embodiment of the present invention, illustrating insertion of the bone anchor within the cannula.

FIG. 9 is a top view of a surgical navigation reference device according to one embodiment of the present invention.

FIG. 10 is a side view of the surgical navigation reference device illustrated in FIG. 9.

FIG. 11 is a side view of the spinal column of a patient, illustrating the percutaneous introduction of the insertion instrument illustrated in FIG. 6 into the patient, with the distal end of the insertion instrument positioned adjacent the iliac crest of the pelvic bone.

FIG. 12 is a side view of the spinal column of the patient illustrated in FIG. 11, illustrating insertion of the bone anchor through the cannula, with the bone engaging portion of the bone anchor threaded into the iliac crest of the pelvic bone.

FIG. 13 is a side view of the spinal column of the patient illustrated in FIG. 11, illustrating coupling of the surgical navigation reference device illustrated in FIGS. 9 and 10 to the mounting instrument illustrated in FIG. 8.

FIG. 14 is a top view of the patient illustrated in FIG. 13, illustrating coupling of the surgical navigation reference device to the mounting instrument, and also illustrating the formation of a surgical incision above the lumbar region of the spinal column at a location remote from the anchoring location.

FIG. 15 is a side view of the spinal column of a patient illustrating the mounting of the surgical navigation reference device shown in FIGS. 9 and 10 to an anterior portion of the iliac region of the patient's pelvic bone.

FIG. 16 is an anterior view of the spinal column shown in FIG. 15, illustrating the mounting of the surgical navigation reference device to the anterior portion of the iliac region of the pelvic bone.

FIG. 17 is an anterior view of the patient illustrated in FIGS. 15 and 16, illustrating the formation of a minimally invasive surgical incision suitable for performance of an image-guided surgical procedure on the lumber region of the spinal column which includes the insertion of a spinal implant into an intervertebral disc space using an anterior surgical approach.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation on the scope of the invention is hereby intended, and that alterations and further modifications in the illustrated devices and further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring to FIGS. 3-8, shown therein is surgical instrumentation according to one form of the present invention for use in association with the percutaneous mounting of a surgical navigation reference device to a patient. Although the instrumentation and methods illustrated and described herein are directed to surgical procedures involving the spinal column, it should be understood that applications of the present invention may extend to surgical procedures outside of the spinal field, including surgical procedures involving the cranium, other types of bones, and/or other anatomical components.

Referring specifically to FIGS. 3 and 4, shown therein is a cannula 50 according to one embodiment of the present invention. The cannula 50 extends along a longitudinal axis L and is generally comprised of an elongate tube 52 and a coupling mechanism 54. The elongate tube 52 defines a passage 56 formed entirely therethrough and extending generally along the longitudinal axis L. As will be discussed in further detail below, the axial passage 56 provides a percutaneous passageway or portal for insertion of a bone anchor into the patient for subsequent anchoring to bone. Although the cannula tube 52 is illustrated as having a cylindrical configuration, it should be understood that other shapes and

configurations are also contemplated as falling within the scope of the invention. As will also be discussed in further detail below, the coupling mechanism 54 is adapted for engagement with an image navigation reference device to mount the image navigation reference device in a substantially fixed position relative to the patient's bone.

The elongate tube 52 of the cannula 50 includes a proximal end portion 60 and a distal end portion 62. The coupling mechanism 54 is preferably attached to the proximal end portion 60 of the tube 52, with the proximal-most end 64 of the tube 52 extending beyond the coupling mechanism 54. The distal end portion 62 of the tube 52 includes a distal-most end 66 that preferably includes one or more anchoring elements 68 configured for contacting and engaging bone to prevent or at least inhibit displacement of the cannula 50 relative to the bone. In one embodiment of the invention, the anchoring elements 68 are serrated teeth extending about the periphery of the distal end 66 of the tube 52. However, it should be understood that other types and configurations of anchoring elements 68 are also contemplated, including a V-shaped wedge configuration or a crescent-shaped configuration. It should also be understood that the distal end 66 of the tube 52 could alternatively define a substantially flat configuration.

The coupling mechanism 54 of the cannula 50 is generally comprised of a mounting block 70 and a fastener 72. The mounting block 70 is preferably attached to the proximal end portion 60 of the tube 52. The mounting block 70 includes a laterally-facing surface 74 that preferably defines a plurality of uniformly spaced, radially-extending splines 76 arranged in a generally circular pattern. An opening 78 extends through the mounting block 70 and is preferably centrally located relative to the circular pattern of radially-extending splines 76. The fastener 72 includes a head 80 and a stem 82, with the stem 82 extending through the

opening 78 in the mounting block 70. The head 80 is preferably over-sized so as to define a thumb-screw arrangement to aid the surgeon in grasping and manipulating the fastener 72. At least the distal end portion 84 of the stem 82 is threaded, the purpose of which will become apparent below.

Referring to FIG. 5, shown therein is a trocar 100 according to one embodiment of the present invention. The trocar 100 extends generally along the longitudinal axis L and includes a proximal end portion 102, an intermediate portion 104 and a distal end portion 106. The proximal end portion 102 preferably includes a stop member 110 and a guide member 112. The stop member 110 has an outer cross section sized somewhat larger than the inner cross section of the axial passage 56 of the cannula tube 52. Additionally, the stop member 110 preferably defines a roughened outer surface 114 to aid the surgeon in grasping and manipulating the trocar 100. In one embodiment, the roughened outer surface 114 is formed by knurling. The guide member 112 preferably defines a relatively smooth outer surface 116 sized and shaped to be slidably received within the axial passage 56 of the cannula tube 52. The intermediate portion 104 is preferably configured as a solid shaft member 120. The distal end portion 106 preferably includes a tip portion 130 and a guide member 132. In a preferred embodiment of the invention, the distal tip portion 130 has a conical-shape defining a pointed tip 134 to facilitate percutaneous insertion through the skin of the patient. However, it should be understood that the distal tip portion 130 can take on other configurations, including a bullet-shape configuration defining a blunted tip to minimize trauma to adjacent tissue. The guide member 132 preferably defines a relatively smooth outer surface 136 sized and shaped to be slidably received through the axial passage 56 of the cannula tube 52.

Referring to FIG. 6, shown therein is the trocar 100 positioned within the cannula 50 to form a percutaneous insertion instrument 150 according to one embodiment of the present invention. The trocar 100 has a length sized to allow the distal tip 130 to extend beyond the distal end 66 of the cannula tube 52. Specifically, the trocar 100 is inserted through the axial passage 56 of the cannula tube 52 until the stop member 110 abuts the proximal end 64 of the cannula tube 52. The stop member 110 thereby ensures proper positioning of the distal tip 130 of the trocar 100 relative to the distal end 66 of the cannula 50. In an alternative embodiment of the invention, the stop member 110 may abut the proximally-facing surface of the cannula mounting block 70 to properly position the trocar 100 relative to the cannula 50. As will be discussed below, when the trocar 100 is properly positioned within the cannula 50, the resulting insertion instrument 150 may be introduced into the patient via percutaneous insertion through the patient's skin. It should be understood that the insertion instrument 150 may also be introduced into the patient via a preformed opening or incision through the patient's skin.

Referring to FIG. 7, shown therein is a bone anchor device 200 according to one embodiment of the present invention. The bone anchor device 200 extends along a longitudinal axis L and is generally comprised of a bone engaging portion 202, a shaft portion 204, a stop member 206, and a handle portion 208. As will be discussed in further detail below, the bone engaging portion 202 of the bone anchor 200 is insertable through the axial passage 56 of the cannula 50 for percutaneous engagement with bone. As will also be described in further detail below, the bone anchor 200 cooperates with the cannula 50 to form a mounting instrument suitable for rigidly mounting an image navigation reference device to the patient.

The bone engaging portion 202 of the bone anchor 200 preferably defines a series of threads 210. However, other means for engaging bone are also contemplated as would occur to one of skill in the art. In one embodiment of the invention, the threads 210 of the bone engaging portion 202 are configured to be self-tapping. In another embodiment of the invention, the threads 210 of the bone engaging portion 202 are configured to be self-drilling. The distal end portion of the bone engaging portion 202 preferably defines a pointed tip 212 to facilitate introduction and penetration into bone, and also preferably includes at least one flute 214 extending across one or more of the threads 210 to facilitate formation of an opening in the bone and the cutting of threads along the opening. In this manner, the bone engaging portion 202 may be engaged to the bone without having to pre-drill an opening and/or pre-cut threads along the opening.

The distal end portion of the shaft 204 preferably includes a guide member 216 that defines a relatively smooth outer surface 218 sized and shaped to be slidably received within the axial passage 56 of the cannula tube 52. The intermediate portion of the shaft 204 preferably includes machine threads 220 defined along a length thereof. The proximal end portion of the shaft 204 preferably includes a connecting portion 224 that defines one or more flats 226 configured for engagement with the handle portion 208.

The stop member 206 preferably includes a threaded axial passage 228 extending therethrough. The threaded axial passage 228 is configured to threadingly engage the machine threads 220 defined along the shaft 204. As should be appreciated, rotation of the stop member 206 about the longitudinal axis L will axially displace the stop member 206 along the shaft 204. In this manner, the axial position of the stop member 206 may be adjusted relative to the shaft 204 and the bone engaging portion 202, the purpose of which

will become apparent below. The outer surface of the stop member 206 preferably includes a number of axial grooves 230 to aid the surgeon in grasping and rotating the stop member 206. In another embodiment of the invention, the outer surface of the stop member 206 may be roughened, such as, for example, by knurling. The distal end portion of the stop member 206 preferably defines a conically-shaped surface 232, the purpose of which will become apparent below.

The handle portion 208 preferably includes a handle 240 and a coupler 242 adapted to releasably couple the handle 240 to the proximal connecting portion 224 of the shaft 204. In one embodiment of the invention, the handle 240 has an axial configuration extending generally along the longitudinal axis L to allow the surgeon to effectively grasp and manipulate the bone anchor 200 and to facilitate driving of the bone engaging portion 202 into bone. However, other handle arrangements are also contemplated as would occur to one of ordinary skill in the art, such as, for example, a T-handle arrangement.

In one embodiment of the invention, the coupler 242 is configured similar to a quick disconnect (QD-type) fitting, whereby axial displacement of the coupler 242 permits the handle 240 to be selectively inserted onto and removed from the shaft 204. Specifically, the coupler 242 defines an axial opening 244 sized to receive the proximal connecting portion 224 of the shaft 204 therein. One or more engaging elements (not shown), such as a number of spherical-shaped balls, are releasably engaged against the flats 226 defined along the connecting portion 224 to releasably connect the handle portion 208 to the shaft 204. The engaging elements (not shown) may be disengaged from the flats 226 via axial displacement of the coupler 242 away from the handle 240, thereby allowing the handle portion 208 to be selectively removed from the shaft 204. The outer surface 246 of the coupler 242 is

preferably roughened, such as by knurling, to allow the surgeon to effectively grasp and axially displace the coupler 242.

Referring to FIG. 8, shown therein is the bone anchor 200 inserted within the cannula 50 to form a mounting instrument 250 according to one embodiment of the present invention. The bone anchor 200 has a length that is sized to allow the bone engaging portion 202 to extend beyond the distal end 66 of the cannula tube 52. Moreover, the distance *d* that the bone engaging portion 202 is permitted to extend beyond the distal end 66 of the cannula tube 52 is limited by abutment of the adjustable stop member 206 against the proximal end 64 of the cannula tube 52. In this manner, the adjustable stop member 206 prevents under insertion and over insertion of the bone engaging portion 202 into bone. As discussed above, rotation of the adjustable stop member 206 correspondingly displaces the adjustable stop member 206 along the shaft 204.

It should be appreciated that adjustment of the axial position of the stop member 206 will correspondingly adjust the distance *d* that the bone engaging portion 202 is permitted to extend beyond the distal end 66 of the cannula tube 52. The conically-shaped surface 232 of the adjustable stop member 206 is partially engaged within the proximal end portion 64 of the cannula tube 52 to securely engage the bone anchor 200 with the cannula 50, thereby providing a substantially rigid mounting instrument 250. Engagement of the conically-shaped surface 232 against the proximal end portion 64 of the cannula tube 52 also aids in co-axially aligning the bone anchor 200 with the cannula 50. In an alternative embodiment of the invention, the stop member 206 may abut the proximally-facing surface of the cannula mounting block 70 to limit the distance *d* that the bone engaging portion 202 is permitted to extend beyond the distal end 66 of the cannula tube 52.

Referring to FIGS. 9 and 10, shown therein is a surgical navigation reference device 300. In one embodiment of the invention, the surgical navigation reference device 300 is a reference frame assembly or another type of reference device suitable for use in association with image navigation systems. In one embodiment, the reference frame 300 is of the passive-type; however, use of an active-type reference frame is also contemplated as falling within the scope of the present invention. The operation and function of the reference frame 300 would be readily apparent to one of skill in the art and therefore need not be discussed in detail herein.

In the illustrated embodiment, the reference frame 300 has a U-shaped or arc-shaped configuration; however, other suitable shapes and configurations are also contemplated as falling within the scope of the invention. Although a specific embodiment of an image navigation reference frame has been illustrated and described herein, it should be understood that other types and configurations of image navigation reference frames are also contemplated, and that the specific embodiment of the reference frame 300 has been included for illustrative purposes only and does not in any way limit the scope of the present invention. Other types and configurations of image navigation reference frames suitable for use in association with the present invention are illustrated and described in U.S. Patent No. 6,226,548 to Foley et al. and U.S. Patent No. 6,236,875 to Burcholz et al., the contents of which are hereby expressly incorporated by reference in their entirety.

As shown in FIGS. 9 and 10, the reference frame 300 includes a U-shaped frame member 302 having a base portion 304 and a pair of leg portions 306, 308 extending from opposite ends of the base portion 304. The U-shaped frame member 302 includes a number of surgical navigation emitters 310 that provide a positive indication of position

and/or movement during an image-guided surgical procedure. The emitters 310 are comprised of LEDs, reflective spherical balls, or any other type of surgical navigation emitter know to those of skill in the art. An emitter 310 is positioned adjacent the distal end of each leg potion 306, 308 and adjacent the interconnection location between the leg portions 306, 308 and the base portion 304. The base portion 304 includes a protuberance or shoulder 312 projecting therefrom in a direction generally opposite the leg portions 306, 308. A calibration divot 314 is centrally located on the shoulder 312. An electrical connector 316 is coupled to the shoulder 312 opposite the calibration divot 314 for connection with an electrical cable 318 (FIG. 10). The cable 318 electrically couples the emitters 310 and the calibration divot 314 to an image navigation control unit (not shown). In another embodiment of the invention, the reference frame 300 may be battery-operated such that no electrical cable 318 is required to directly couple the reference frame 300 to the image navigation control unit.

A coupling mechanism 320 extends from the shoulder 312 and is configured for releasable interconnection with the coupling mechanism 54 of the cannula 50. The coupling mechanism 320 generally includes a block portion 322 and a washer portion 324. The block portion 322 is operatively attached to the shoulder 312, with the washer portion 324 extending laterally from the block portion 322. The washer portion 324 includes a laterally-facing engaging surface 326 defining a plurality of uniformly spaced, radially-extending splines 328 arranged in a circular pattern about the outer periphery of the washer portion 324. The radially-extending splines 328 are configured for interdigitating engagement with the radially-extending splines 76 of the cannula coupling mechanism 54. As will be discussed below, such interdigitating engagement allows the reference frame

300 to be variably positioned at a select angular orientation relative to the longitudinal axis L of the mounting device 250. The washer portion 324 also defines a threaded opening 330 configured to threadingly receive the threaded fastener portion 84 of the cannula coupling mechanism 54 therein to releasably couple the reference frame 300 to the cannula 50. Although a specific embodiment of the coupling mechanism 320 has been illustrated and described herein, it is contemplated that other types and configurations of coupling mechanisms may be used to releasably couple the reference frame 300 to the cannula 50.

As would be appreciated by those of skill in the art, the reference frame 300 cooperates with other components of an image navigation system to provide computer-assisted, image-guided surgery. More specifically, a digital image is generated and displayed on a monitor (not shown) for viewing by the surgeon before and/or during a medical or surgical procedure. The digital image represents at least one anatomical element, such as, for example, a vertebral body, and is produced from an image data set that is typically generated in a pre-operative or pre-procedural setting by a CAT scan or an MRI. The image data set includes multiple reference points corresponding to various portions of the anatomical element. The image navigation system typically includes a digitizer or a sensor array for identifying the relative position of each of the reference points to be displayed by tracking the position of the emitters 310 disposed on the reference frame 300. The image navigation system also includes a processor, such as, for example, a programmable controller or another type of computer processor for modifying the image data set according to the identified relative position of each of the reference points during the surgical procedure. The position of a surgical instrument, such as, for example, a probe or drill, may also be tracked by the sensor array relative to the anatomical element. Further features and aspects regarding the

componentry and the general operation and function of surgical navigation systems are well known to those of skill in the art and therefore need not be discussed in further detail herein.

Having described various embodiment of surgical instrumentation suitable for use in association with the percutaneous mounting of an image navigation reference frame to a patient, reference will now be made to a method for accomplishing the same. Referring to FIGS. 11-14, collectively shown therein is a method for percutaneously mounting the image navigation reference frame 300 to a patient according to one form of the present invention. The cannula 50, the trocar 100, the bone anchor 200 and the reference frame 300 are all initially sterilized as per standard operating practice. Pursuant to standard operating procedure, the patient is given a general anesthetic and is preferably secured in a relatively motionless position relative to a support structure, such as, for example, an operating table. A surgical positioning frame or another type of stabilizing device may be used to help maintain the patient in a fixed position and orientation during the mounting of the reference frame 300 and throughout the surgical procedure.

In a preferred embodiment of the invention, the image navigation reference frame 300 is anchored to bone at a location remote from the surgical site. In image-guided surgical procedures performed adjacent the patient's spinal column, the reference frame 300 is preferably anchored to bone at a location remote from the patient's spine. In one embodiment of the invention, the reference frame 300 is anchored to the patient's pelvic bone P, and more particularly the iliac region of the pelvic bone P. In a more specific embodiment of the invention, the reference frame 300 is anchored to the iliac crest IC of the pelvic bone P. Although the reference frame 300 has been illustrated and described as being mounted to certain portions and locations of the patient's anatomy, it should be understood that the

reference frame 300 may be anchored to other skeletal members and positioned adjacent other anatomical components.

One advantage of anchoring the reference frame 300 to the patient's pelvic bone P, and more particularly to the iliac crest IC, is that such an anchoring technique will likely result in reduced trauma to the patient. Additionally, anchoring the reference frame 300 to the iliac crest IC or other portions of the pelvic bone P will typically require a lesser degree of accuracy and precision as compared with other anchoring techniques involving more delicate areas of the patient's anatomy, such as, for example, a vertebral body. As a result, the risk of injury or complications resulting from mounting of the reference frame 300 to the patient can be significantly reduced. For purposes of comparison, the prior art surgical navigation system illustrated in FIG. 2 teaches anchoring of the reference frame 20 directly to the vertebra V_A. As discussed above, engagement of the reference frame 20 to the spinous process 28 of the vertebra V_A may result in damage or trauma to the vertebral bone, particularly when dealing with older patients or patients afflicted with bone weakening diseases. Moreover, engagement of the reference frame 20 directly to the vertebra V_A requires a relatively high degree of precision and accuracy to avoid damage to adjacent neural structures, blood vessels and other delicate tissues.

Referring to FIG. 11, shown therein is the insertion instrument 150 percutaneously introduced through the skin S of the patient and positioned adjacent the iliac crest IC of the pelvic bone P. Specifically, the trocar 100 is initially positioned within the cannula 50 with the trocar tip 130 extending beyond the distal end 66 of the cannula tube 52 to form the insertion instrument 150 (See FIG. 6). As would be apparent to one of skill in the art, the insertion instrument 150 may then be percutaneously introduced into the patient in a

minimally invasive manner. As discussed above, in an alternative embodiment of the invention, the insertion instrument 150 may be introduced into the patient via a preformed opening or incision through the skin S. Upon introduction of the insertion instrument 150 into the patient, the distal end 66 of the cannula tube 52 is preferably positioned in abutment against bone, with the teeth or serrations 68 securely engaging the bone to substantially prevent displacement of the cannula tube 52. Following the percutaneous introduction of the insertion instrument 150 into the patient, the trocar 150 is removed from the cannula 50, thereby establishing a percutaneous portal through the patient's skin S to a location adjacent the iliac crest IC of the pelvic bone P.

Referring to FIG. 12, the bone engaging portion 202 of the bone anchor 200 is inserted through the percutaneous portal established by the cannula tube 52 and is anchored to the iliac crest IC. As discussed above, in one embodiment of the invention, the bone engaging portion 202 defines a series of threads 210, a pointed tip 212, and a flute 214 extending across one or more of the threads 210 (See FIG. 7). As a result, the bone engaging portion 202 is capable of forming a threaded opening in the bone without the need for additional surgical instrumentation such as a bone drill and/or a bone tap. In this manner, the bone engaging portion 202 is both self-drilling and self-tapping. However, it should be understood that other configuration of the bone engaging portion 202 are also contemplated as would occur to one of ordinary skill in the art, including configurations that do not have self-drilling and/or self-tapping features. The pointed tip 212 of the bone engaging portion 202 aids in initial penetration of the bone anchor 200 into bone and also facilitates threading advancement of the bone engaging portion 202 through the bone. The flute 214 extending across the threads 210

provides the bone engaging portion 202 with the capability to cut threads into the bone and to channel bone material and other debris out of the threading opening.

Once the pointed tip 212 is positioned against the bone, rotation of the handle 240 about the longitudinal axis L threadingly engages the bone engaging portion 202 into the iliac crest IC of the pelvic bone P. As discussed above, the distance *d* that the bone engaging portion 202 is permitted to extend beyond the distal end 66 of the cannula tube 52 is limited by abutment of the conical surface 232 of the adjustable stop member 206 against the proximal end 64 of the cannula tube 52 (See FIG. 8). In this manner, the adjustable stop member 206 prevents over-insertion and under-insertion of the bone engaging portion 202 relative to the bone. As should be appreciated, adjustment of the axial position of the adjustable stop member 206 will correspondingly adjust the distance *d* that the bone engaging portion 202 is permitted to extend beyond the distal end 66 of the cannula tube 52.

Referring to FIG. 13, the bone engaging portion 202 is threadingly advanced into the iliac crest IC of the pelvic bone P until the conical surface 232 of the adjustable stop member 206 engages the proximal end 64 of the cannula tube 52. Continued threading advancement of the bone engaging portion 202 into the bone will cause the teeth or serrations 68 formed at the distal end 66 of the cannula tube 52 to bite into the outer surface of the bone to firmly secure the mounting instrument 250 to the iliac crest IC. At this point, the bone engaging portion 202 extends into the iliac crest IC at the proper depth or distance *d*. With the bone engaging portion 202 threadingly engaged to bone and the adjustable stop member 206 engaged tightly against the proximal end 64 of the cannula tube 52, the mounting instrument 250 in turn becomes rigidly attached to the iliac crest IC. The handle 240 of the bone anchor 200 may then be removed from the end portion 224 of the shaft 204 by axially displacing the

coupler 242 away from the handle 240. Removal of the handle 240 from the remainder of the bone anchor 200 provides the mounting device 250 with a lower profile, thereby reducing the likelihood of interfering with or otherwise hindering the surgeon or other medical personnel during the surgical procedure. Upon completion of the surgical procedure, the handle 240 may once again be re-inserted back onto the end portion 224 of the shaft 204 to provide a means for unthreading and removing the bone anchor 200 from the iliac crest IC.

Following rigid attachment of the mounting instrument 250 to the iliac crest IC, the reference frame 30 is connected to the mounting device 250 by engaging the coupling mechanism 320 of the reference frame 300 with the coupling mechanism 54 of the cannula 50. Specifically, the radially-extending splines 328 of the coupling mechanism 320 (Figs. 9 and 10) are engaged with the radially-extending splines 76 of the coupling mechanism 54 (FIGS. 3 and 4) in an interdigitating manner. With the radially-extending splines 76, 328 intermeshed with one another, the threaded stem portion 84 of the fastener 72 is threaded into the threaded opening 330 of the coupling mechanism 320 to fixedly mount the reference frame 300 at a select angular disposition relative to the mounting instrument 250. Specifically, the U-shaped frame member 302 of the reference frame 300 extends along a transverse axis T that is arranged at an angle α relative to the longitudinal axis L of the mounting instrument 250. As should be apparent, the interdigitating engagement between the coupling mechanism 54 and the coupling mechanism 320 permits the reference frame 300 to be selectively disposed within a range of angles α relative to the mounting instrument 250. In one embodiment of the invention, the angle α falls within a range of about 90 degrees to about 150 degrees. In a more specific embodiment, the angle α is about 130 degrees. It should be understood, however, that the angle α may take on other values as well, including angles less

than 90 degrees and greater than 150 degrees. As should also be apparent, the reference frame 300 may be easily removed from the mounting instrument 250 by simply unthreading the fastener 72 from the threaded opening 330.

With the reference frame 300 rigidly secured to the mounting instrument 250, the patient is scanned and imaged with a CAT scan, an MRI or any other suitable scanning procedures to generate a field of view sufficiently large to display the spinal anatomy and the reference frame 300. The scanned radiographic image is then loaded into a surgical navigation system processor (not shown). Typically, the scanning process takes place in a scanning room or a similar facility. Following scanning, the patient is transferred to an operating room or a similar facility. Once in the operating room, the scanned radiographic image may be displayed on a monitor for viewing by the surgeon before and/or during an image-guided surgical procedure. In one embodiment of the invention, the pre-procedural scanned image is used throughout the image-guided surgical procedure. However, it should be understood that in other embodiments of the invention, intra-procedural scans may be taken to verify or update the pre-procedural scanned image.

Referring to FIG. 14, in one embodiment of the present invention, a surgical incision I_{MIN} is formed at a location remote from the anchoring location of the reference frame 300. Positioning of the reference frame 300 at a location remote from the surgical incision I_{MIN} provides the surgeon with an unobstructed area above and adjacent the surgical site. As a result, the surgeon may perform the surgical procedure without having to manipulate around or be encumbered/hindered by the reference frame 300 and/or the mounting instrument 250. For purposes of comparison, the prior art navigation system illustrated in FIG. 2 positions the reference frame 20 directly above the surgical incision I, thereby creating a structural

obstruction to the surgical site which may interfere with the surgical procedure or otherwise hinder the surgeon during the surgical procedure.

In the illustrated embodiment, the surgical incision I_{MIN} is formed adjacent the patient's spinal column for performing an image-guided surgical procedure on or around one or more of the patient's vertebrae V. It should be understood, however, that the surgical incision I_{MIN} may be formed at other locations for performing an image-guided surgical procedures on or around other anatomical components. After forming the surgical incision I_{MIN}, the surgeon may perform an image-guided surgical procedure on the patient through the surgical incision I_{MIN}. However, in applications involving fluoroscopic surgery or other types of percutaneous surgery, the image-guided surgical procedure may be performed through a small opening formed through the skin S of the patient, thereby eliminating the need to form a surgical incision I_{MIN}.

Notably, the size of the surgical incision I_{MIN} need only be large enough to provide the surgeon with sufficient access to the surgical site. In this manner, the image-guided surgical procedure may be performed in a minimally invasive manner. For purposes of comparison, the image navigation system illustrated in FIG. 2 requires a large surgical incision that must not only provide sufficient access to the surgical site, but which must also be sized to accommodate anchoring of the reference frame 20 to the vertebra V_A. As should be appreciated, large surgical incisions are highly invasive and can result in increased trauma, blood loss, post-operative pain, and a lengthy recovery period.

In a preferred embodiment of the invention, the surgical incision I_{MIN} is formed subsequent to anchoring of the reference frame 300 to the patient. In this manner, the surgeon need not necessarily be present during acquisition of the radiographic images and/or during

other pre-operative procedures. Moreover, anchoring of the reference frame 300 to the iliac crest IC can be performed in an environment requiring a lesser degree of sterilization than that normally associated with the formation of a surgical incision and/or commencement of a surgical procedure. For example, full draping is not necessarily required during anchoring of the reference frame 300 to the patient and/or during acquisition of the radiographic images. For purposes of comparison, as illustrated in FIG. 2, anchoring of the reference frame 20 to the vertebra V_A must be done in an intra-procedural following formation of the surgical incision I by the surgeon. As a result, the overall length of the surgical procedure is increased, thereby tending to increase the overall risk of infection. Moreover, following formation of the surgical incision I, the surgeon must wait around while other medical personnel acquire the radiographic images of the vertebra V_A, thereby resulting in inefficient use of the surgeon's time.

As would be apparent to one of skill in the art, during the initial stage of an image-guided surgical procedure, the surgeon touches a surgical instrument or pointer having a tracking emitter attached thereto to the calibration divot 314 to register the location of the reference frame 300 in the navigation system processor. Since the reference frame 300 is maintained in a substantially fixed position relative to the patient's spinal anatomy, the particular position of spinal components may also be registered in the navigation system processor. Based upon the registered position of the spinal components, the image navigation processor generates and illustrates the pre-procedural scanned image of the spinal components on a monitor that is viewable by the surgeon. For additional positioning information, wires or screws equipped with emitters can be affixed to one or more spinal elements to provide data corresponding to the actual position and orientation of the patient's spinal column. This real-

time measured data can be compared with the scanned data and, if necessary, the position and/or orientation of the patient may be manipulated by the surgeon until the measured data corresponds to that of the scanned data.

As would be apparent to one of skill in the art, the position of a surgical instrument fitted with one or more emitters can be tracked in three-dimensional space relative to the patient's spinal anatomy in real time. Such surgical instruments include, for example, distractors, drills, reamers, drivers, forceps, or any other type of surgical instrument that would be apparent to one of skill in the art. Various medical and surgical procedures may then be performed on the patient's spinal anatomy by using image-guided technology. For example, a discectomy may be performed on one or more of the patient's vertebrae V via an image-guided surgical procedure to remove at least a portion of the natural intervertebral disc. Additionally, endoscopes or biopsy probes can be inserted into the patient's spine via the image-guidance system. Various types of spinal implants may also be inserted into or attached to one or more of the vertebrae V via an image-guided surgical procedure. As would be apparent to one of skill in the art, the implant may itself be fitted with one or more emitters such that the implant may tracked in space relative to the spinal anatomy. Such implants include, for example, fusion devices, spacers, artificial discs, screws, rods, hooks, plates, wires, or other types of implants or devices typically used in association with treatment of the spine.

Referring to FIGS. 15-17, shown therein is a method for performing image-guided spinal surgery on a patient according to another form of the present invention. As will be discussed in further detail below, in one embodiment of the invention, the method includes mounting an image navigation reference frame 300 to the patient's pelvic bone P at a

location remote from the spinal column, accessing a portion of the spinal column from an anterior direction, and performing an image-guided surgical procedure on the spinal column via an anterior surgical approach. In a specific embodiment of the invention, the image-guided surgical procedure includes the removal of a portion of a natural intervertebral disc from the lumbar region of the spinal column to form an intervertebral opening, followed by insertion of a spinal implant into the intervertebral opening via an anterior surgical approach. It should be understood, however, that other surgical procedures and techniques are also contemplated as falling within the scope of the present invention, including, for example, surgical procedures and techniques involving other regions and/or portions of the spinal column, or other anatomical regions or components.

Referring to FIGS. 15 and 16, in the illustrated embodiment of the invention, the patient is situated in a supine position (e.g., facing up) with an image navigation reference frame 300 mounted to bone at a location remote from the patient's spinal column and in a substantially fixed position relative to the spinal column. Although the illustrated embodiment of the invention depicts the use of a single image navigation reference frame 300, it should be understood that the use of multiple image navigation reference frames is also contemplated as falling with the scope of the present invention.

The image navigation reference frame 300 is preferably mounted to the patient's pelvic bone P. In one embodiment of the invention, the image navigation reference frame 300 is mounted to the iliac region of the pelvic bone P, and more specifically to the iliac crest IC. In a further embodiment of the invention, the image navigation reference frame 300 is mounted to an anterior portion of the pelvic bone P, and more specifically to an anterior portion of the iliac crest IC. However, it should be understood that the reference

frame 300 may alternatively be mounted to other portions of the iliac crest IC or to other regions of the pelvic bone P. For example, if the patient is situated in a face down position, the reference frame 300 may be mounted to a posterior portion of the iliac crest IC (as illustrated in FIG. 13), or to other regions of the pelvic bone P. Additionally, if the patient is situated in a lateral position (not shown), the reference frame 300 may be mounted to any portion of the iliac crest IC or to other regions of the pelvic bone P. Furthermore, although the reference frame 300 has been illustrated and described as being mounted to specific portions and locations of the patient's anatomy, it should be understood that the reference frame 300 may be mounted to other skeletal members and/or other anatomical components at locations remote from the spinal column.

In the illustrated embodiment of the invention, anterior mounting of the reference frame 300 to the iliac crest IC may be accomplished by way of the same devices and procedures illustrated and described above with regard to the posterior mounting of the reference frame 300 to the iliac crest IC. Specifically, in one embodiment of the invention, the reference frame 300 is percutaneously mounted to the pelvic bone P. Similar to the procedure illustrated in FIG. 11 and described above, the insertion instrument 150 is percutaneously introduced through the skin S of the patient in a minimally invasive manner to position the distal end 66 of the cannula 50 into engagement with bone. The trocar 150 is removed from the cannula 50, thereby establishing a percutaneous portal through the patient's skin S to a location adjacent the bone, such as, for example, locations adjacent an anterior portion of the iliac crest IC. Additionally, similar to the procedure illustrated in FIGS. 12 and 13, the bone engaging portion 202 of a bone anchor 200 is inserted through the percutaneous portal established by the cannula 50 and driven into secure engagement

with bone. The adjustable stop member 206 is tightly engaged against the proximal end 64 of the cannula 50, thereby forming a substantially rigid mounting device 250. As illustrated in FIGS. 15 and 16, the resulting mounting device 250 is securely anchored to an anterior portion of the iliac crest IC.

Following anchoring of the mounting device 250 to the iliac crest IC, the reference frame 300 is connected to the mounting device 250 by engaging the coupling mechanism 320 of the reference frame 300 with the coupling mechanism 54 of the cannula 50, the details of which have been illustrated and described above. As a result, the reference frame 300 is securely mounted to the iliac crest IC of the pelvic bone P in a substantially fixed position relative to the spinal column. As discussed above, other types and configurations of mounting devices and reference frames are also contemplated for use in association with the present invention as would occur to one of skill in the art.

Once the reference frame 300 is securely coupled to the mounting device 250, which in turn is anchored to the iliac crest IC of the pelvic bone P, the patient is scanned and imaged with a CAT scan, an MRI or any other suitable scanning procedures to generate a field of view sufficiently large to display a portion of the spinal column and the adjacent anatomy. The scanned radiographic image is then loaded into a surgical navigation system processor (not shown) and may be displayed on a monitor for viewing by the surgeon before and/or during an image-guided surgical procedure. In one embodiment of the invention, the pre-procedural scanned image is used throughout the image-guided surgical procedure. However, it should be understood that in other embodiments of the invention, intra-procedural scans may be taken to verify or update the pre-procedural scanned image.

Referring collectively to FIGS. 15-17, in one embodiment of the present invention, an image-guided surgical procedure is performed on a portion of the spinal column using an anterior surgical approach (i.e., approaching the spinal column in the general direction of arrow A shown in FIG. 15). The surgical procedure initially involves accessing a portion of the spinal column from an anterior direction. In one embodiment of the invention, access to the spinal column is provided by forming one or more surgical incisions in an area adjacent the spinal column, such as, for example, in an area adjacent the lumber region of the spinal column. However, as should be appreciated, one or more surgical incisions may also be formed adjacent other regions of the spinal column, including the cervical and thoracic regions, to provide access to areas adjacent other portions of the spinal column.

In a preferred embodiment of the invention, access to the spinal column is provided by forming one or more minimally invasive surgical incisions I_{MIN}. The size of the surgical incision I_{MIN} is largely dictated by the space requirements for accommodating the manipulation and/or placement of various surgical instruments, implant components, and/or other devices required for the surgical procedure. As should be appreciated, large surgical incisions are highly invasive and can result in increased trauma, blood loss, post-operative pain, and a lengthy recovery period. As a result, minimally invasive surgical equipment and procedures may be used to reduce the size and/or the number of surgical incisions.

In one embodiment of the invention, performance of the image-guided surgical procedure on the spinal column is accomplished through the minimally invasive surgical incision I_{MIN}. In other embodiments of the invention, the image-guided surgical procedure

may be performed percutaneously through a small portal or tube extending through the skin S of the patient, also tending to minimize trauma, blood loss, post-operative pain, and the length of the recovery period. However, as should also be appreciated, reducing the size of the surgical incision or portal may also have the effect of decreasing the surgeon's ability to directly visualize the internal anatomy adjacent the surgical site as well as the instrumentation, components and/or other devices used in association with the surgical procedure. The use of a surgical image navigation technology may therefore be helpful to aid the surgeon in performing various surgical steps and procedures involving the preparation of the anatomy and/or the insertion and manipulation of surgical instruments, components and/or other devices relative to the spinal column.

The reference frame 300 is preferably positioned and oriented so as to provide the surgeon with a relatively unobstructed area above and adjacent the surgical incision I_{MIN}. As a result, the surgeon may perform the surgical procedure without having to manipulate around or be encumbered/hindered by the reference frame 300 and/or the mounting device 250. In a preferred embodiment of the invention, the surgical incision I_{MIN} is formed subsequent to the mounting of the reference frame 300 to the patient. In this manner, the surgeon need not necessarily be present during acquisition of the radiographic images and/or during other pre-operative procedures. Moreover, anchoring of the reference frame 300 can be performed in an environment requiring a relatively lesser degree of sterilization compared with that normally associated with the formation of a surgical incision and/or the commencement of a surgical procedure. For example, full draping is not necessarily required during anchoring of the reference frame 300 to the patient and/or during acquisition of the radiographic images. After forming the surgical incisions I_{MIN}, the

surgeon may then perform an image-guided surgical procedure on the spinal column using an anterior surgical approach.

As illustrated in FIGS. 16 and 17, in one embodiment of the invention, the image-guided surgical procedure performed on the spinal column comprises a disc replacement procedure. As would be apparent to one of skill in the art, disc replacement procedures are commonly used in the total or partial replacement of a degenerated, damaged or ruptured natural intervertebral disc with various types of artificial disc prostheses. In the illustrated embodiment of the invention, the disc replacement procedure is performed in the lumbar region of the spinal column, and more particularly in association with the disc space D between the fourth and fifth lumbar vertebrae L4-L5. However, it should be understood that in other embodiments of the invention, the disc replacement procedure may be performed in other regions of the spinal column, including the cervical and thoracic regions of the spinal column. Additionally, it should also be understood that the disc replacement procedure may be performed in association with the intervertebral disc space between any adjacent pair of vertebrae, such as, for example, the third and fourth lumbar vertebrae L3-L4 or the fifth lumbar vertebra L5 and the first sacral segment S1.

Following are various surgical steps or techniques that may be used in association with a disc replacement procedure using an anterior surgical approach according to one embodiment of the present invention. However, it should be understood that other steps and techniques may be used in performing a disc replacement procedure using an anterior surgical approach, and that the present invention is in no way limited to the surgical steps and techniques to be discussed below. Further details regarding other surgical steps and techniques for performing spinal surgery using an anterior surgical approach are illustrated

and described in U.S. Patent No. 6,375,655 to Zdeblick et al., the contents of which are hereby incorporated by reference in their entirety.

A disc replacement procedure typically involves the initial removal of at least a portion of the natural intervertebral disc from the disc space D to form an intervertebral opening between the adjacent vertebrae. Initially, a dilator, distractor or a similar type of instrument is typically inserted between the vertebral end plates of the adjacent vertebral bodies to dilate or distract the disc space D. The distal portion of an outer sleeve, tube or sheath may then be inserted into the disc space D to positively engage the anterior aspect of the adjacent vertebral bodies to firmly, but temporarily, anchor the sleeve in position. In essence, the sleeve provides a protected working channel to shield and/or guide various instruments, implants and/or other surgical devices or components. A reamer, drill or any another type of cutting instrument may be extended through the outer sleeve to form an opening or cutout between the adjacent vertebral bodies that is sized and configured to receive the spinal implant therein. If the spinal implant is threaded, the intervertebral opening can be tapped to facilitate threaded insertion of the spinal implant between the vertebral bodies. An example of a procedure for forming an intervertebral opening across a disc space and details regarding associated instrumentation are described in U.S. Patent No. 5,484,437 to Michelson, the contents of which are hereby incorporated by reference in their entirety.

Following formation of the intervertebral opening within the disc space D, a spinal implant 400 may then be inserted into the intervertebral opening via an anterior surgical approach with the aid of a computer-controlled, image-guided surgical navigation technology. The spinal implant 400 is typically engaged by an insertion instrument, driver

or a similar device to aid the surgeon in inserting and manipulating the spinal implant 400 through the outer sleeve and into the desired position and orientation relative to the intervertebral opening in the disc space D. As will be discussed below, the precise position and orientation of the spinal implant 400 and/or the surgical instrumentation or other surgical components or devices can be monitored and verified via electronic feedback provided by the image navigation system.

In one embodiment of the invention, the spinal implant 400 comprises an artificial disc prosthesis that is sized and configured for insertion within the intervertebral opening formed in the disc space D. The spinal implant 400 may be designed and configured to facilitate arthrodesis or fusion between the adjacent vertebrae, or may be designed and configured to allow a degree of articular movement between the adjacent vertebrae to mimic the normal bio-mechanical motion provided by a natural intervertebral disc. An example of a fusion-type spinal implant suitable for use in association with the present invention is illustrated and described in U.S. Patent No. 6,375,655 to Zdeblick et al., the contents of which have been incorporated by reference in their entirety. An example of an articulation-type spinal implant suitable for use in association with the present invention is illustrated and described in U.S. Patent No. 5,562,738 to Boyd et al., the contents of which are hereby incorporated by reference in their entirety. It should be understood that the spinal implant 400 may take on a variety of shapes and configurations without detracting from the scope of the present invention. For example, the spinal implant 400 may have a generally rectangular configuration, a kidney-shaped configuration, an irregular configuration, a cylindrical configuration, a conical or tapered configuration, or any other shape or configuration that would be apparent to one of skill in the art.

As should be appreciated, the spinal implant 400 can be fitted with one or more emitters for tracking in two-dimensional or three-dimensional space relative to the patient's anatomy or other surgical instruments/devices/components used in association with spinal surgery. For example, the spinal implant 400 may be fitted with one or more emitters such that the spinal implant 400 may be tracked and navigated in two-dimensional or three-dimensional space relative to the spinal column, and more specifically the intervertebral disc space D being treated. Via the use of image-guided navigation technology, the spinal implant 400 may be inserted into the intervertebral opening in the disc space D and manipulated/adjusted to the appropriate position and/or orientation with a high degree of accuracy and precision. As should be appreciated, the precise positioning and orientation of the spinal implant 400 within the disc space D may be crucial to the overall success of a disc replacement procedure. Additionally, surgical instruments, such as, for example, guide tubes, distractors, reamers, drills, taps, drivers, inserters, or any other type of surgical device or component may be fitted with one or more emitters for tracking in two-dimensional or three-dimensional space relative to the patient's anatomy, the spinal implant 400 or other surgical instruments/devices/components used in association with spinal surgery. Several examples of surgical instruments and devices that may be operatively fitted with one or more image navigation emitters are illustrated and described in U.S. Patent No. 6,348,058 to Melkent et al., the contents of which are hereby incorporated by reference in their entirety.

As would be apparent to one of skill in the art, during the initial stage of an image-guided surgical procedure, the surgeon may touch a surgical instrument or pointer having a tracking emitter attached thereto to a calibration divot to register the location of the

reference frame 300 or other reference components in the navigation system processor (not shown). Since the reference frame 300 is maintained in a substantially fixed position relative to the pelvic bone P and the spinal column, the particular position and orientation of these anatomic structures may also be registered in the navigation system processor. The particular position and orientation of a selected region of the spinal column may then be tracked and monitored throughout the surgical procedure. Based on the registered position of the pelvic bone P and the spinal column, the image navigation processor generates and illustrates the pre-procedural scanned image of these components on a monitor that is viewable by the surgeon. For additional positioning information, wires or screws equipped with emitters can be affixed to other bones or anatomic structures to provide additional data corresponding to the actual position and orientation of the patient's spinal column. This real-time measured data can be compared with the scanned data and, if necessary, the position and/or orientation of the patient may be manipulated by the surgeon until the measured data corresponds to that of the scanned data.

Although the illustrated embodiment of the invention is directed to an image-guided spinal disc replacement procedure, it should be understood that other surgical procedures and techniques associated with the spinal column are also contemplated as falling within the scope of the present invention. Additionally, although the illustrated embodiment of the invention is directed to an image-guided surgical procedure associated with the lumbar region of the spine, it should be understood that the present invention may also be used in association with other regions of the spinal column, including the cervical or thoracic regions of the spinal column. Moreover, although the illustrated embodiment of the invention is directed to an image-guided surgical procedure associated with the

spinal column, it should be understood that the present invention may also be used in association with image-guided surgical procedures on or around other joints and/or anatomical components.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiments have been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.